

## **REMARKS**

In the Office Action dated January 29, 2004, claims 15, 3-10 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Paltieli in view of Yanof et al.. The Examiner acknowledged that the Paltieli reference does not teach a mixing unit connected to the imaging unit for mixing a representation of the tip into the 2D image and, if the tip is not located in the image plane, for mixing a designation of the distance of the tip from the image plane into the 2D image, wherein the designation is alterable and indicates a magnitude of the distance, as claimed in independent claim 15. The Examiner relied on the Yanof et al reference as teaching a stereo tactic system having a mixing unit for creating a composite image of the location of the tip as well as the tube of an instrument. The Examiner stated that the Yanof et al reference teaches that if the tip is not located in an image plane, but is instead located a distance away, a designation of the distance of the tip from the image plane is mixed into the 2D image. For this teaching, the Examiner cited the trajectories and the indicia demonstrating the distance from each of these slices composing the volumetric image in Yanof et al, in Figure 4 and in the passage at column 7, lines 33-65.

The Examiner stated it would have been obvious to a person of ordinary skill in the art to modify the Paltieli system in accordance with these teachings of Yanof et al, to allow for better position monitoring of the instrument during surgery to improve interventional guidance.

This rejection is respectfully traversed for the following reasons.

In Figure 4 of the Yanof et al reference and the associated passage cited by the Examiner, the only procedure described is an operation planning procedure,

performed by an operation planning system 102. The operation planning procedure is illustrated using a number of patient volumes formed by slice images and including a *virtual* needle 120 (emphasis added). The operation planning system 102 has a device with a D-shaped gap 104, which defines a linearly proceeding trajectory. This linear trajectory proceeds through each of the slice images, with the intersections of the trajectory with the respective image planes of the slice images being emphasized by points in Figure 4 of Yanof et al. There is no teaching in the Yanof et al reference, however, to specify a distance of the tip of the aforementioned virtual needle 120 from the image plane of the slice image, and to mix a designation of that distance into one of the slice images for navigation purposes. Since such a distance is not mixed into any of the slice images, the Yanof et al reference does not provide a teaching that this distance value designation should change, given a change of the position of the instrument relative to the slice plane of the slice image.

The absence of these teachings is because the Yanof et al reference, or at least the passage cited by the Examiner, is for a completely different purpose from navigation. As noted above, the aforementioned procedure in the Yanof et al reference is for operation planning, and is not for the purpose of guiding or navigating an instrument relative to a patient. The needle 104 is a virtual needle that is used solely for operation planning. This virtual needle is not intended to represent a "real" needle or other instrument, and is only for the purpose of defining the aforementioned linear trajectory. Navigation of the "real" needle relative to the patient with a navigation system, much less the mixing of a designation of the distance of the tip of the real needle from an image plane, are nowhere mentioned in the Yanof et al reference.

Mixing of a virtual needle 154 into a slice image is, in fact, described in Figure 5 (top left image) of Yanof et al, and the associated description at column 8, lines 14-24, when the needle is located outside of the patient volume. When this occurs, an "out of range" designation is displayed. Nevertheless, there is no indication or designation of the distance of the needle from any of the image planes of the slice images, which is precisely the information that is needed to assist in navigation.

Therefore, even if the Paltieli system were modified in accordance with the teachings of Yanof et al, this would merely incorporate a procedure for operation planning into the Paltieli reference as described in Yanof et al, but still would not satisfy the language of independent claim 15, nor claims 3-10 and 31 depending therefrom. None of those claims, therefore, would have been obvious to a person of ordinary skill in the field of the design of medical navigation systems based on the teachings of Paltieli and Yanof et al.

Claims 32 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Paltieli and Yanof et al, further in view of Manwaring et al. The Examiner relied on the Manwaring et al. reference as teaching a display designation in the form of a circle having a diameter that is alterable according to the magnitude of a distance. Applicants do not dispute that the Manwaring et al reference provides such a teaching, however, for the reasons noted above, there is no reason why a person of ordinary skill in the field of medical navigation system design would modify the Paltieli/Yanof et al combination to employ such a display designation, because there is no teaching in either of those references to include any designation, in any form, of the distance of the tip of the instrument from the image plane of the slice image. Therefore, even though the Manwaring et al reference discloses a way of

visually designating distance information, there is no distance information displayed in the Paltieli/Yanof et al combination, and therefore there is no need to modify the Paltieli/Yanof et al combination in accordance with the teachings of Manwaring et al. Manwaring et al teach away of displaying information that does not exist in the display that would result from a combination of Paltieli and Yanof et al.

Claims 32 and 33, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Paltieli, Yanof et al and Manwaring et al.

Claims 16, 17, 21 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cosman in view of Graumann.

This rejection is respectfully traversed for the following reasons.

The Cosman reference discloses no more than a system for positioning and repositioning a patient with regard to a treatment or imaging device, using a number of cameras that record both the patient and the treatment or imaging device, as well as the positioning device on which the patient is disposed. The Cosman reference is not concerned at all with navigating a medical instrument relative to a patient. Claim 16 has been amended to specifically refer to the "first subject" as being the patient and the "second subject" as being a medical instrument adapted for insertion into the patient. Applicants submit that a person of ordinary skill in the field of medical navigation system design would not even have a basis to consult the Cosman reference, since that reference is concerned solely with radiation therapy, rather than any type of instrument navigation.

The Graumann reference discloses a C-arm x-ray apparatus with which a 3D image can be reconstructed from a series of 2D projections. The Graumann

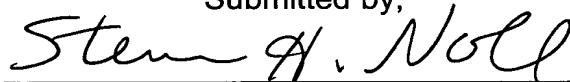
reference is concerned only with the manner by which the 3D image can be reconstructed from the series of 2D x-ray projections acquired from different directions, and provides no teachings at all with regard to navigation of any sort, and in particular provides no teachings with regard to mixing an image of a medical image into the acquired or reconstructed 3D image.

Therefore, even if the Cosman reference were modified in accordance with the teachings of Graumann, Applicants are unable to find any teaching in either reference regarding navigation of a medical instrument that is adapted for insertion into the patient.

Claims 16, 17, 21 and 22, therefore, would not have been obvious to a person of ordinary skill in the field of medical navigation system design under the provisions of 35 U.S.C. §103(a) based on the teachings of Cosman and Graumann.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



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